

## DATA EVALUATION RECORD

1. **CHEMICAL:** Tebuthiuron. Shaughnessey Number: 105501.
2. **TEST MATERIAL:** Tebuthiuron, N-[5-(1,1-dimethylehtyl)-1,3,4-thiadiazol-2-yl]-N,N'dimethylurea, 99.1% purity, colorless solid.
3. **STUDY TYPE:** Avian Dietary LC<sub>50</sub> Test.  
Species tested: Mallard Duck (Anas platyrhynchos).
4. **CITATION:** Negilski, D.S. et al. 1988. The Toxicity of Tebuthiuron to Juvenile Mallards in a Five-Day Dietary Study. Study performed by Toxicology Division, Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, Indiana. Submitted by Elanco Products Company.
5. **REVIEWED BY:**  
  
Tracy L. Perry  
Wildlife Biologist  
EEB/EFED  
  
Signature: Tracy L. Perry  
Date: 5/29/91
6. **APPROVED BY:**  
  
Henry T. Craven  
Head, Section IV  
EEB/EFED  
  
Signature: Henry Craven  
Date: 5/29/91
7. **CONCLUSIONS:** The study is scientifically sound and fulfills the requirements for an avian dietary LC<sub>50</sub> test. With a LC<sub>50</sub> of greater than 5093 ppm, tebuthiuron is considered to be practically non-toxic to the mallard duck.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. MATERIALS AND METHODS:

A. Test Animals: The birds used in this study were 4-day-old mallard ducks, ranging in weight from 36.0g to 50.0g. Two-day-old ducklings were obtained from Whistling Wings, Hanover, Illinois and transferred to pens for a 2-day acclimation period. During this period, ducklings had free access to TEKLAD diet and Greenfield city water. A photoperiod of 24 hours of light was maintained via fluorescent bulbs. Ducklings were evaluated daily for abnormal behavior or physical injury.

B. Test System: Test pens were made out of stainless steel and measured 75 x 43 x 28 cm (W x L x H). Relative humidity ranged from 30% to 45%. Greenfield city water and TEKLAD feed were provided ad libitum. A photoperiod of 24 hours of light was maintained throughout the study.

C. Dosage: The nominal concentrations chosen for the study were 0 (control), 600, 1200, 2500, and 5000 ppm. Test diets were analyzed for tebuthiuron concentration immediately after diet preparation. The stability and homogeneity of tebuthiuron in the avian diet were also measured.

D. Design: Two replicates of the diet control and each dietary concentration were performed. Birds were randomly assigned, regardless of sex, to one of 10 pens (5 birds per pen). Each bird was uniquely identified with a wing tag. Birds were observed at least twice daily for signs of toxicity and mortality. Individual body weights were recorded at test initiation (day 0), test day 5, and at the termination of the test (day 8). Food consumption was measured during the treatment and basal diet phases of the test (test days 5 and 8).

E. Statistics: Mean body weight, body weight gain and food consumption were statistically analyzed using Dunnett's 't' test.

12. REPORTED RESULTS:

Analyses of freshly prepared diets indicated that tebuthiuron concentrations ranged from 97% to 103% of

nominal concentrations. Nominal concentrations of tebuthiuron were: 0.0 (control), 600, 1200, 2500, and 5000 ppm. Measured concentrations of tebuthiuron in the diet were: none detected (control), 583, 1176, 2578, and 5093 ppm. Tebuthiuron was found to be evenly distributed and stable (ranging from 98 - 100% of initial concentration after one week) in the diet.

No mortalities or behavioral signs of toxicity were noted throughout the study.

During the five-day treatment phase, there was no significant difference between the mean body weight gain values of control birds and birds at the 583 ppm test level. However, birds exposed to diets containing tebuthiuron concentrations of >1176 ppm gained significantly less weight as compared with the control group. During the three-day basal diet phase, there were no significant differences in mean body weight gain values of control and treatment birds (Table 2, attached).

During the five-day treatment phase, birds in the 2578 ppm and 5093 ppm test groups ate significantly less food than control birds. Birds at the 1176 ppm treatment level also consumed less food than control birds, although this difference was not significantly significant. During the three-day basal diet phase, birds at the 2578 and 5093 ppm test levels consumed less food than control birds; however, these differences were not statistically significant (Table 3, attached).

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The avian dietary LC<sub>50</sub> of tebuthiuron, performed on February 25 to March 4, 1988, was found to be greater than 5093 ppm (measured concentration).

A Good Laboratory Practice Statement complying with FIFRA, 40 CFR, Part 160 was signed by the study director. A Quality Assurance Statement, signed by the quality assurance officer, reported that GLP standards were followed except for the fact that the test article characterization was not available prior to the study. However, the characterization was completed and a reference was included in the report.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedures:

Test procedures were in accordance with Subdivision E and SEP Guidelines with the following minor exceptions:

- a) Laboratory temperatures were not included in the report.
- b) Ducklings were 4-days-old at test initiation vs. the recommended 5-10 days.
- c) No necropsies were performed (recommended, not mandatory).

**B. Statistical Analysis:** EEB concurs with the study author's finding of a  $LC_{50}$  value of >5093 ppm.

**C. Discussion/Results:** With an  $LC_{50}$  of >5093 ppm, the test material is considered to be practically non-toxic to the mallard duck.

This study is scientifically sound and meets the requirements for an avian dietary study.

**D. Adequacy of the Study:**

- (1) Classification: Core.
- (2) Rationale: N/A
- (3) Repairability: N/A

15. **COMPLETION OF ONE-LINER:** Yes, May 22, 1991.

TABLE 2. AVERAGE BODY WEIGHTS OF JUVENILE MALLARDS FED DIETS CONTAINING  
TEBUTHIURON (EL-103, COMPOUND 75503). STUDY NO. A00288.

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Measured Dietary Concentration (ppm)	Initial Number of Birds	Mean Body Weight $\pm$ SD (g/bird)			Mean Body Weight Gain $\pm$ SD (g/bird)	
		Test Day			Treatment Phase	Basal Diet Phase
		Initial	5	8	(5 Days)	(3 Days)
0.0 (Control)	10	42.5 $\pm 4.2$	102.0 $\pm 17.4$	159.5 $\pm 35.9$	59.5 $\pm 14.5$	57.5 $\pm 22.5$
583	10	43.9 $\pm 4.6$	106.1 $\pm 12.0$	162.5 $\pm 26.6$	62.2 $\pm 10.8$	56.4 $\pm 15.8$
1176	10	42.9 $\pm 3.6$	89.8 $\pm 14.5$	139.4 $\pm 33.6$	46.9* $\pm 12.6$	49.6 $\pm 20.4$
2578	10	43.7 $\pm 3.4$	81.5* $\pm 8.3$	129.2* $\pm 17.8$	37.8* $\pm 7.3$	47.7 $\pm 12.0$
5093	10	42.6 $\pm 4.4$	67.3* $\pm 8.0$	111.3* $\pm 15.0$	24.7* $\pm 7.1$	44.0 $\pm 9.8$

\* Statistically significant difference between this value and the control ( $P \leq 0.05$ ).

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TABLE 3. FOOD CONSUMPTION BY JUVENILE MALLARDS FED DIETS CONTAINING  
TEBUTHIURON (EL-103, COMPOUND 75503). STUDY NO. A00288.

Measured Dietary Concentration (ppm)	Number <sup>a</sup> of Pens	Mean Food Consumption $\pm$ SD (g/bird/day)			
		Treatment Phase		Basal Diet Phase	
		5 Days	% of Control	3 Days	% of Control
0.0 (Control)	2	21.8 $\pm 1.2$	100	47.4 $\pm 8.7$	100
583	2	20.7 $\pm 2.5$	95	44.6 $\pm 1.3$	94
1176	2	17.4 $\pm 1.8$	80	49.4 $\pm 0.9$	104
2578	2	13.4* $\pm 2.5$	61*	34.7 $\pm 14.3$	73
5093	2	8.3* $\pm 1.2$	38*	27.6 $\pm 0.0$	58

<sup>a</sup> Five birds per pen.

\* Statistically significant difference between this value and the control ( $P \leq 0.05$ ).